

(b) *Classification*. (1) Class II (special controls). The barium enema retention catheter and tip with or without a bag that is a gastrointestinal tube and accessory is exempt from the premarket notification procedures in subpart E of this part subject to the limitations in § 876.9.

(2) Class I (general controls) for the dissolvable nasogastric feed tube guide for the nasogastric tube. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[49 FR 573, Jan. 5, 1984, as amended at 65 FR 2317, Jan. 14, 2000; 65 FR 76932, Dec. 8, 2000]

#### § 876.5990 Extracorporeal shock wave lithotripter.

(a) *Identification*. An extracorporeal shock wave lithotripter is a device that focuses ultrasonic shock waves into the body to noninvasively fragment urinary calculi within the kidney or ureter. The primary components of the device are a shock wave generator, high voltage generator, control console, imaging/localization system, and patient table. Prior to treatment, the urinary stone is targeted using either an integral or stand-alone localization/imaging system. Shock waves are typically generated using electrostatic spark discharge (spark gap), electromagnetically repelled membranes, or piezoelectric crystal arrays, and focused onto the stone with either a specially designed reflector, dish, or acoustic lens. The shock waves are created under water within the shock wave generator, and are transferred to the patient's body using an appropriate acoustic interface. After the stone has been fragmented by the focused shock waves, the fragments pass out of the body with the patient's urine.

(b) *Classification*. Class II (special controls) (FDA guidance document: "Guidance for the Content of Premarket Notifications (510(k)'s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.")

[65 FR 48612, Aug. 9, 2000]

## PART 878—GENERAL AND PLASTIC SURGERY DEVICES

### Subpart A—General Provisions

Sec.

878.1 Scope.

878.3 Effective dates of requirement for premarket approval.

878.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

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### Subpart D—Prosthetic Devices

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878.3500 Polytetrafluoroethylene with carbon fibers composite implant material.

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878.3590 Ear prosthesis.

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878.3680 Nose prosthesis.

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878.4040 Surgical apparel.

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878.4160 Surgical camera and accessories.

878.4200 Introduction/drainage catheter and accessories.

878.4300 Implantable clip.

878.4320 Removable skin clip.

878.4350 Cryosurgical unit and accessories.

878.4370 Surgical drape and drape accessories.

878.4380 Drape adhesive.

878.4400 Electrosurgical cutting and coagulation device and accessories.

878.4440 Eye pad.

878.4450 Nonabsorbable gauze for internal use.

878.4460 Surgeon's glove.

878.4470 Surgeon's gloving cream.